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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,010	02/02/2001	Gregory Bruce Wilson	0179/61248-A/JPW/BJA	7419

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Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
LI, BAO Q	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/776,010	**Applicant(s)** WILSON ET AL.	
	Examiner Bao Qun Li	**Art Unit** 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *32-33, 36-40, 42-43, and 46-47*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: PTO-892.

Bao Qun Li

Advisory Action

The response to the final action filed on 06/16/2005 under 37 CFR 1.116 has been noted. However, the amendment of the claims has been considered and entered, but is not deemed to place the application in condition for allowance.

For purpose of appeal, the status of the claims is as follows:

Allowed claim(s): NONE.

Rejected claim (s): 32-33, 36-40, 42-43, 46-47.

Claim(s) objected to: NONE.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 32-40, 42-43 and 46-47 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (Patent No. 4,816, 563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86).

3. Applicants traverse the rejection and submit that Wilson and Ablashi in combination did not teach the composition comprising HHV-6A and HHV-6B specific transfer factor. Whereas, the composition disclosed in the prior art comprises more than that two transfer factor. Therefore, it differs from the claimed composition in the current application. Moreover, the applicants note that applicants' claimed invention clearly has a much better efficacy (90%) than the transfer factor of Ablashi et al. The rejection should be withdrawn.

4. Applicants' argument has been fully considered; however, it is not found persuasive because: 1). The claimed composition does not cite that it only comprises only two kinds of transfer factors against HHV-6A and HH6V6. The language of "consisting essential of" still read on the composition comprising other components besides the transfer factor against HHV-6A or

HHV-6B. Because Ablashi et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV. The TF is extracted from spleens of BALB/c mice immunized wit EBV, CMV, and HHV-6 live virus, in which the HHV-6 include HHV-6A and HHV-6B. While Ablashi et al. do not teach to use cell free product secreted from a mammal, Wilson et al. disclose a method for producing an antigen specific excreted transfer factor (TF) from a colostrums or milk of a bovine, and it can be produced in larger quantity and processed in a lyophilized form stored for later use and/or reconstituted in sterile pyrogen-free water, physiologic saline or any other fluid suitable for injection or oral administration (lines 26 on col. 5 through line 68 on col. 6). Wilson et al. also teach that the antigen specific TF is used for enhancing the cellular immunity against specific antigens to which the TF-producing animal is immunized, such as herpes simplex virus. 2). The specification does not teach that the claimed composition is able to produce much better efficacy (90%) than the transfer factor of Ablashi et al. It only teaches that majority of CFS patients and MS patients showed an increase in NK cell function of 50% or greater (See lines 23-32 on page 12.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 32-40, 42-43 and 46-47 are still rejected under 35 U.S.C. 102(b) as being anticipated by Advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 17, Fall Issue 1998, p 29) in view of Advertisement by Chisolm Biological Laboratory in Positive Health News, Fall, 1997, p. 27).

1. Applicants traverse the rejection and submit that the cited reference does not teach every limitations of claimed invention in that it does not teach that TF is isolated from a bovine

immunized with HHV-6A or HHV-6B. Applicants further argue that the product cited by the applicants is derived from chicken bursas.

2. Applicants' argument has bee fully considered; however, it is not found persuasive because the massager delivered by the advertisement indicates that the ImmunFactor is a colostrums product, which is not a simply dried colostrums/whey products and it is a particular colostrums product comprising an antigen specific transfer factor (TF) with an immunological stimulatory function specific against particular antigen(s), including HHV6. The product produced by Chisolm Biological Laboratory comprising the TF against both HHV-6A and HHV-6B. This evidence is further substantiated by the news letter produced by the same company, which clearly states that such product comprising TF against HHV-6A and HHV-6B was going to be produced in the fall of 1998, and the HHV-6A and HHV-6B TFs are particularly useful for treating AIDS and CFS (See attached news letters 1998, report No. 16 on page 2, 2nd column).

3. Therefore, the rejection is maintained.

Conclusion

4. Therefore, the rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li (M.D)
07/10/2005

JAMES HOUSEL 7/11/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600